

Seminar Series

# REGULATORY AFFAIRS

## ANIMAL HEALTH



# Elements of Data Management



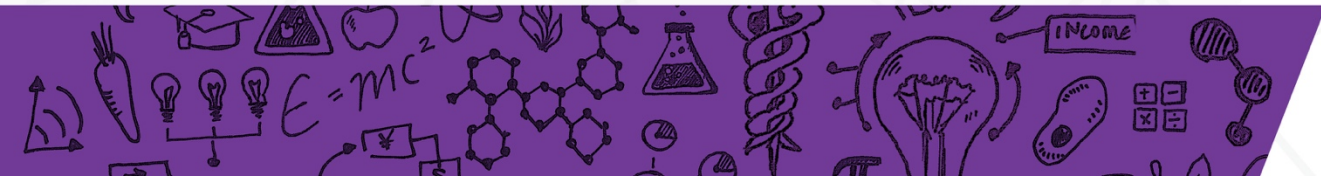
**KANSAS STATE**  
UNIVERSITY

Olathe

# Elements of Data Management

## Disclaimers:

- The views in this presentation represent those of the presenter and not necessarily those of Bayer, CVM, SQA or KSU.
- Names used in examples are fictional and not based on real people. The use of these fictional names is solely for providing fictional examples in this presentation.



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# Elements of Data Management

## Overview:

- Why is data management so important?
- Who should most be concerned with data management?
- Where does data management fit?
- Organization of data management.
- Highlights:
  - Raw Data.
  - Form Design.
  - In life.
  - Data for submission.



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# Elements of Data Management

## Why is data management so important?



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# Elements of Data Management

## **FDA BIMO inspection findings continue to involve:**

- Recordkeeping.
- Inclusion/Exclusion Criteria Issues.
- Informed Consent Issues.
- Dosage Issues.
- IP accountability.
- Analytical Concerns (validation, stability).

Presented by Chrissy J. Cochran, PhD, Director, OBIMO/ORR/FDA  
2018 SQA Annual Meeting



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# Elements of Data Management

## **FDA CVM QASR Findings continue to involve:**

- Animal accountability, especially for those removed from study.
- Inadequate monitoring/QA.
- Final Study Report does not accurately reflect the raw data.
- Lack of documentation of sample handling from necropsy to freezing (residue studies).
- Test article not able to be reconciled.

Presented by Michelle Kornele, DVM, QA Team Leader and  
Debi Garvin, MS, RQAP-GLP, GLP/GCP Quality Assurance Specialist  
2017 SQA Annual Meeting



# Elements of Data Management

## Ultimately why is this so important?

- Our customers, our patients, and their owners are relying on us to be sure our products are safe and effective.
- Good decisions cannot be made with poor data.



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# Elements of Data Management

**Who in Animal Health should be most concerned with data management?**



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# Elements of Data Management

## FDA BIMO inspections in FY2017 occurred at:

Center	CBER	CDER	CDRH	CVM
CI	84	525	209	13
Sponsor	3	81	48	1
GLP	0	31	6	8
Total	97	1109	302	22

- Total includes numbers from other inspectional areas not performed by CMV and therefore not included (IRB, BA/BE, etc)

Presented by Chrissy J. Cochran, PhD, Director, OBIMO/ORR/FDA  
2018 SQA Annual Meeting



# Elements of Data Management

While the majority of BIMO inspections occurred at Clinical Investigator sites, who is responsible for the quality and integrity of the data when submitted to the agency? The Sponsor 😊

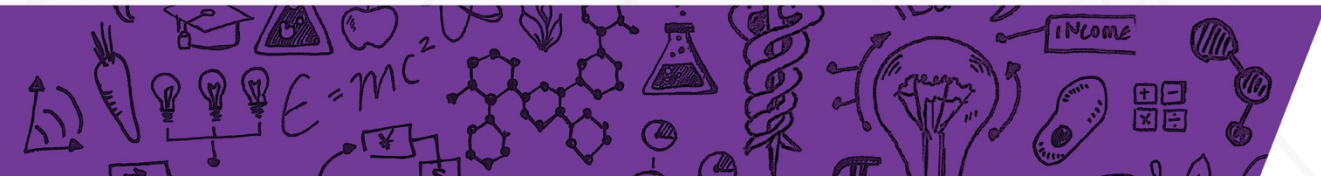


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# Elements of Data Management

## Where does data management fit in?



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# Elements of Data Management

## Data Management is linked to:

- Data Privacy
- Data Management Plans
- Vendor Management
- Data Acquisition
- Electronic Data Capture
- CRF Completion Guidelines
- Vendor Selection
- Database Validation
- Database Programming
- Laboratory Data Handling
- External Data Transfers
- Presentations at Investigator Meetings
- Training
- Metrics for Clinical Trials
- Assuring Data Quality
- Measuring Data Quality
- Data Storage
- Data Entry Processes
- Medical Coding Dictionary Management Safety Data
- Management and Reporting Serious Adverse Event
- Data Reconciliation
- Database Closure
- Clinical Data Archiving

Selection from SCDM Good Clinical Data Management Practices, October 2009 Edition TOC



# Elements of Data Management

## Data Management is linked to DQ & DI

- Data Quality
  - ALCOA
    - Attributable
    - Legible
    - Contemporaneous
    - Original
    - Accurate
- Data Integrity
  - CCAE
    - Complete
    - Consistent
    - Available
    - Enduring

However elements from both lists are inextricably linked.  
You can't have quality or integrity without the other



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# Elements of Data Management

## Organization of data management



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# Elements of Data Management

## Who is “Data Management”?

- Data management is the sum of the processes you wrap around your data to ensure the integrity of your data.
- The centralization of management of these processes may be the responsibility of a group called “Data Management”.
- Clinical and Operational vs Information Services and Infrastructural.



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# Elements of Data Management

## Who is “Data Management”?

- Optimally, data management would be an entity involved in study processes, that has a complete investment in the integrity of the data, but separated from the assessment or conclusion of study results.
  - However, it is critical to acknowledge that all individuals involved in studies contribute to the data integrity.



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# Elements of Data Management

## Who is “Data Management”?

- In companies with the size and resources, a Data Management unit is often associated with either Statistics or Information Services.
- Based on company size or structure, this may not always be possible. Data management may be more of a process with responsibilities assigned to site personnel, study directors, sponsor personnel, etc.
  - One size does not fit all.



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# Elements of Data Management

## Who is “Data Management”?

- Data Management ensures data integrity.
- Everyone is responsible.
- All personnel should be trained in detecting data integrity issues.
  - Employees.
  - Temporary Staff.
  - Contractors.
  - Anyone involved in creation, modification, retention or protection of data.
- Everyone should have awareness for detecting issues.
- Everyone should know how to report issues.



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# Elements of Data Management

## Highlights of how data management facilitates study design, conduct and reporting

- Raw Data.
- Form Design.
- In life.
- Data for submission.



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# Elements of Data Management

## Raw Data



# Elements of Data Management

## Data Management can help determine what is your raw data

- Raw data is defined as the original record (data) which can be described as the first-capture of information, whether recorded on paper or electronically.
  - May include true copies (complete and accurate copies of raw data).
  - Information that is originally captured in a dynamic state should remain available in that state.

Medicines & Healthcare products Regulatory Agency (MHRA) 'GXP' Data Integrity Guidance and Definitions; Revision 1: March 201



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# Elements of Data Management

## Determining what is your raw data

- For data to be raw data it must include the metadata.
- Data about data that provides context and meaning.
  - “1” could be a data point.
  - Metadata could include:
    - “g” if it is a weight.
    - “John Smith” to indicate who recorded it.
    - “08 April 2018” to indicate the date recorded.
    - “2” if this was corrected from 2 to 1, reason for change, initials and date of correction (aka – the audit trail).

1



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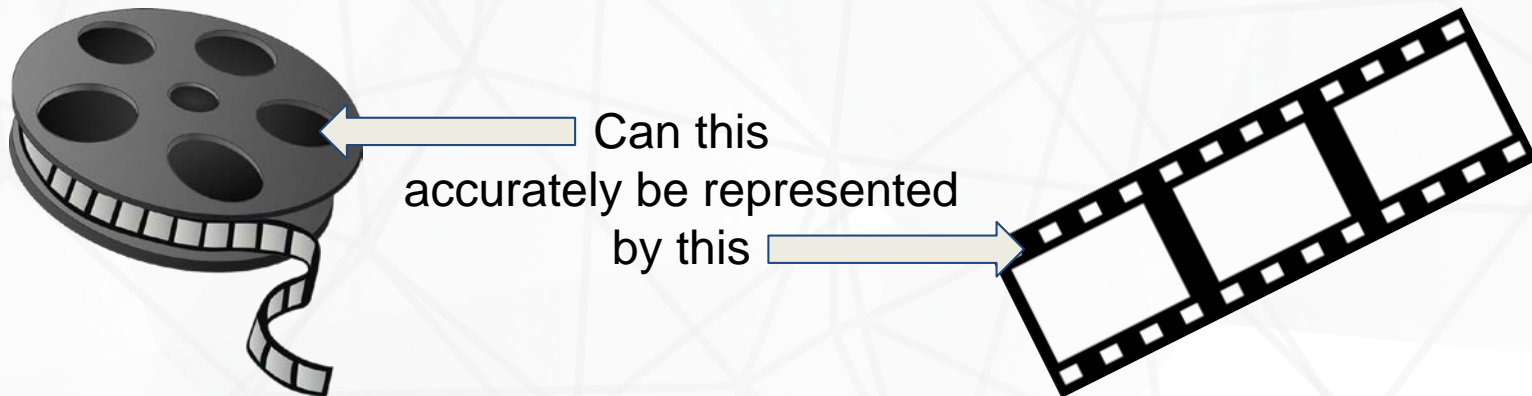
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# Elements of Data Management

## Determining what is your raw data

- Static True Copies of Dynamic Raw Data.



- “To enable a GXP compliant record this approach is likely to be demanding in its administration.”



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# Elements of Data Management

## Form Design





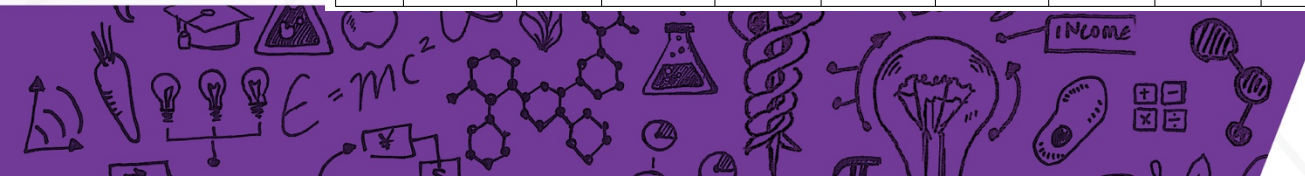
# Elements of Data Management

## Form Design

- Should ensure forms:
  - Collect the data we need to evaluate the product
  - Collect all the data specified in the protocol.
  - Collect the data as specified in the protocol.
  - Collect the data in a way that will work for the people capturing the data in the field.
  - Are not be limited by design to only please the protocol author.
  - When possible also work for data entry people (art form).

Temperature (°F)*
_____.

										Scored by (initial)	Rectal Temp Read by (initial)	Recorded by (initial)



# Elements of Data Management

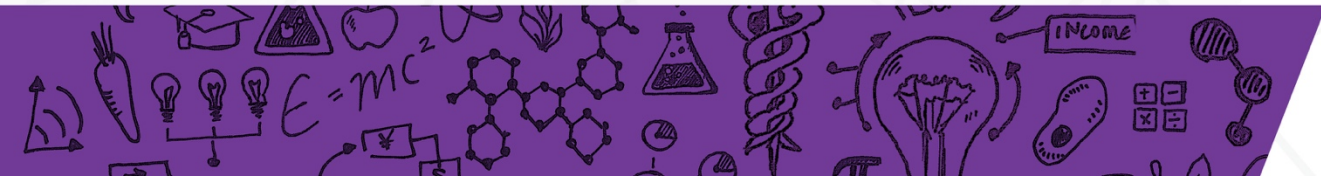
## Form Design

- Should make sense.
  - No “entries by omission”.
  - No entries that require interpretation.
  - No “on the spot calculations” – capture the raw data.
    - PE – HR or RR
    - Exceptions when professional evaluations are performed
      - BRD evaluation scoring

Blood Sample Collected (check)	VS	Blood Sample Collected (check)
<input type="checkbox"/>		<input type="checkbox"/> YES <input type="checkbox"/> NO

\_\_\_\_\_ breaths in 15 secs

X 4 = \_\_\_\_\_ breaths per minute



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# Elements of Data Management

## Form Design

- Ensure EDC systems do not restrict answers site staff can provide in a way that introduces bias into the clinical study.
  - Can be true for paper also.

Compared to last visit how much better does the cat appear?

- Slightly better
- Moderately better
- Majorly better



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# Element of Data Management

## Form Design

Privacy considerations

- Is this data really needed?
- Does the collection of needed data compromise privacy?
- Is the collection of the data acceptable in all countries with study sites?



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# Elements of Data Management

**In life**



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# Elements of Data Management

## In life

- Assist with providing monitoring reports
- QC assistance
- Database and user issue investigations
- Tracking trends
- Tracking study progress.
  - Enrollment success.
  - Completion vs failure to complete ratios and why.
  - Supplying data for interim analysis.
    - Gatekeeper for eager statisticians.



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# Elements of Data Management

## Data for Submission



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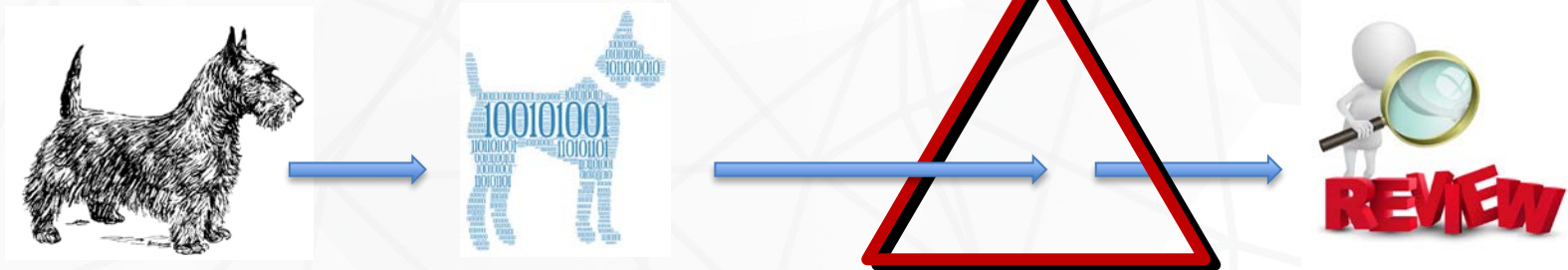
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# Elements of Data Management

## Determining how to get you the CVM deliverables

- Data file types accepted by e-Submitter:
  - PDF
  - XML
  - XPT



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# Elements of Data Management

## Determining how to get you the CVM deliverables

XML

### Form 3: Daily Observation Record

Date	<input type="text" value="13/07/2016"/>	*	▶
	13-Jul-2016		
Time	<input type="text" value="10:26"/>		▶
	<input checked="" type="checkbox"/> Yes		▶
	<input type="checkbox"/> No		
	<input type="text"/>		▶
	<input type="text" value=""/>		▶

```
- <StudyEventData StudyEventOID="Day_13">
  - <FormData FormOID="Daily_obs" m:FormStatus="Complete Final" TransactionType="Insert">
    - <AuditRecord>
      <UserRef UserOID="██████████"/>
      <LocationRef LocationOID="██████████"/>
      <DateTimeStamp>2016-07-13T14:28:38.703</DateTimeStamp>
    </AuditRecord>
    - <ItemGroupData ItemGroupOID="Daily_obs_1" TransactionType="Insert">
      <ItemDataDate ItemOID="COLDT" TransactionType="Insert">2016-07-13</ItemDataDate>
      <ItemDataTime ItemOID="COLTM" TransactionType="Insert">05:26:00.0000000-05:00</ItemDataTime>
      <ItemDataBoolean ItemOID="NORMAL" TransactionType="Insert">true</ItemDataBoolean>
      <ItemDataString ItemOID="PERFORM" TransactionType="Insert">██████████</ItemDataString>
    </ItemGroupData>
  </FormData>
</StudyEventData>
```



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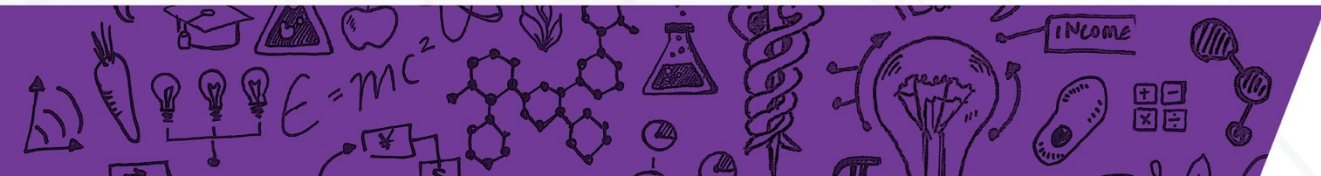
# Elements of Data Management

## Determining how to get you the CVM deliverables

XML

Session	Participation	FirstName	LastName
U1	Presenter	Arnie	Ansel
U1	Attendee	Billy	Bateson
U1	Attendee	Chad	Calloway

```
<?xml version="1.0" encoding="UTF-8" standalone="true"?>  
- <CONFERENCE xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">  
  - <REGISTRATION>  
    <SESSION>U1</SESSION>  
    <PARTICIPATION>Presenter</PARTICIPATION>  
    <FIRSTNAME>Arnie</FIRSTNAME>  
    <LASTNAME>Ansel</LASTNAME>  
  </REGISTRATION>  
  - <REGISTRATION>  
    <SESSION>U1</SESSION>  
    <PARTICIPATION>Attendee</PARTICIPATION>  
    <FIRSTNAME>Billy</FIRSTNAME>  
    <LASTNAME>Bateson</LASTNAME>  
  </REGISTRATION>  
  - <REGISTRATION>  
    <SESSION>U1</SESSION>  
    <PARTICIPATION>Attendee</PARTICIPATION>  
    <FIRSTNAME>Chad</FIRSTNAME>  
    <LASTNAME>Calloway</LASTNAME>  
  </REGISTRATION>  
</CONFERENCE>
```




# Elements of Data Management

## Determining how to get you the CVM deliverables

### New CVM e-Submitter questions

Was an Electronic Data Capture (EDC) system used to collect data?


Yes  
 No

 Enter each EDC system used to collect data in section 3.4.1 "Electronic Data Captures (EDC) System".

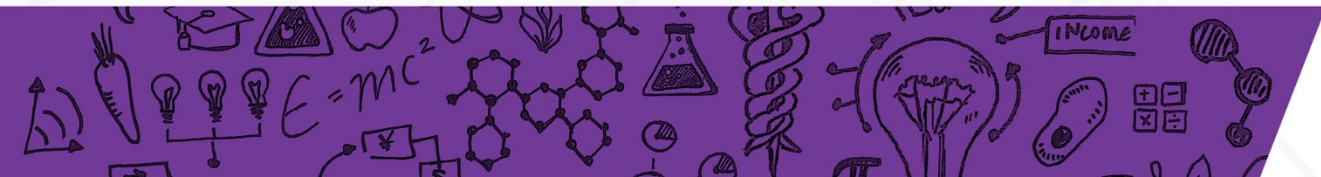
Enter each EDC system used to collect data...

Was an Electronic Data Capture (EDC) system used to collect data?

Yes  
 No

 Describe how the attributes of ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) were maintained for any non-EDC collected data during the internal handling of the files through the submission of data files to CVM.

Describe how the attributes of ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) were maintained for any non-EDC collected data during the internal handling of the files through the submission of data files to CVM.



# Contact Information



**Damon Bradley**

Research & Regulatory Systems Data Manager,  
Clinical Development NA

Bayer US, LLC  
Animal Health

[damon.bradley@bayer.com](mailto:damon.bradley@bayer.com)

913-268-2307



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